15. The method of claim 14 wherein the virus is Hepatitis C Virus (HCV).

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16. The method of claim 15 further comprising encouraging treating of the virus in combination therapy with an interferon.

REMARKS

Allowable Subject Matter

Claims 1-10 were all rejected for technicalities, not substantive rejections. Terminal disclaimers are filed concurrently herewith, and those claims are narrowed further herein.

Double Patenting Rejection

Claims 1, 3, and 5 were rejected as comprising non-statutory double patenting. The applicant disagrees because the scope of these claims is different from any claims previously issued. (See below). The proper response is therefore submission of Terminal Disclaimers, which are filed concurrently herewith. The applicant further contemplates that the newly added claims will also be considered to comprise non-statutory double patenting, but these claims are covered by the same Terminal Disclaimers.

Current Claims Are All Narrower Than Issued Claims of Patents in The Family

The family of the current application includes three issued patents: a great-grandparent application 09/590449 (issued as US 5767097); a grand-parent application 09/987450 (issued as US 6063772); and a parent application 09/156646 (issued as US 6150337).

Independent claim 1 is amended herein to clarify that administration of ribavirin according to the claim includes a volitional step. The ribavirin is being added in a dosage "to" (i.e., for the purpose of) promoting the Type 1 response and suppressing the Type 2 response, rather than merely at a dosage "which" promotes Type 1 and suppresses Type 2 response. The claim is thus narrower than that issued as claim 1 from the great-grandparent application, and should therefore be readily allowed.

> US 5767097, claim 1. A method of modulating Th1 and Th2 response in activated T cells of a human patient comprising administering Ribavirin to

> the T cells in a dosage which promotes the Th1 response and suppresses the Th2 response.

Dependent claim 2 exactly tracks the dosages set forth in claims 4 and 5 of US 6063772, with the exception that the units μg/ml should obviously have been μM, as corrected in the parent application that issued as US 6150337.

> US 6063772, Claim 4. The method of claim 1 wherein the dosage range achieves a blood serum level in the patient averaging approximately 0.25-6.7 μg/ml of ribavirin.

> US 6063772, Claim 5. The method of claim 1 wherein the disease comprises Hepatitis C and the dosage range achieves a blood serum level in the patient averaging approximately 0.25-6.7 μg/ml of ribavirin.

Independent claim 3 is similarly amended herein to clarify that administration of ribavirin includes a volitional step. The ribavirin is being added under a protocol "intended to" (i.e., for the purpose of) promote the Type 1 response and suppress the Type 2 response, rather than merely under a protocol "sufficient to" promote Type 1 and suppress Type 2 response. The claim is thus narrower than that issued as claim 6 from the great-grandparent application, and should therefore be readily allowed.

> US 5767097, Claim 6. A method of treating a patient having a disease which includes a viral component and a non-viral component, the non-viral component being characterized by reduced Th1 levels and increased Th2 levels in activated T-lymphocytes, comprising administering Ribavirin to the patient under a protocol sufficient to promote the Th1 response and suppress the Th2 response in a patient.

Dependent claim 4 tracks the additional limitation of adding an interferon alpha, as recited in 9 of US 6063772.

> US 6063772, Claim 9. The method of any of claims 1-7 further comprising administering interferon alpha to the patient.

Independent claim 5 is similarly amended herein to clarify that administration of ribavirin includes a volitional step. The ribavirin is being added under a protocol "for the purpose of " increasing the Type 1 response and suppressing the Type 2 response, rather than merely under a protocol "which" increases the Type 1 and suppress the Type 2 responses. The claim is thus narrower than that issued as claim 5 from the parent application, and should therefore be readily allowed.

> US 6159337, Claim 5. A method of inhibiting a virus by growing a virus in an environment having lymphocytes which produce Type 1 and Type 2 cytokine responses, and adding ribavirin to the environment in a concentration which increases the Type 1 response and suppresses the Type 2 response.

Dependent claim 6 adds the limitation that the virus comprises Hepatitis C, which tracks claim 2 of US 6063772.

> US 6063772, Claim 2. The method of claim 1 wherein the disease comprises Hepatitis C.

Dependent claims 7-10 merely focus on the environment in which the virus is growing in hepatocytes or liver. The specification is replete with reference to the application of ribavirin to hepatocytes or liver.

Newly Added Claims Area All Readily Allowable Over the Prior Art

As mentioned over the phone, the three issued patents in this family are being litigated. One of the positions being pursued by the alleged infringers is that some of the claims are limited by file wrapper estoppel, on the grounds that the applicant voluntarily canceled some dependent claims during prosecution of the parent application 09/156646. Indeed, the applicant canceled claims 16-18 during the 09/156646 prosecution in response to obviousness rejections. But the canceled claims were dependent on allowed claim 15, and were canceled because the applicant

couldn't seem to convince the examiner that it is wrong to reject a claim on the grounds of obviousness if the canceled claim is dependent on an allowed claim.

Newly added claim 11 reinstates the rejected dependent subject matter. Claim 11 herein is basically claim 15 of the parent application (issued as claim 5 in US 6150337), with the added limitations that: (a) "a virus" is "HCV"; (b) an interferon alpha is also added; and (c) the additions are made with the expectation of increasing the Type 1 response and suppressing the Type 2 response.

> US 6150337, claim 5, and 09/156646 application claim 15. A method of inhibiting a virus by growing **a virus** in an environment having lymphocytes which produce Type 1 and Type 2 cytokine responses, and adding ribavirin to the environment in a concentration which increases the Type 1 response and suppresses the Type 2 response.

Previously canceled claims 16, 18 recited:

> 09/156646 application claim 16. The method of claim 15 wherein the virus comprises Hepatitis C.
>
> 09/156646 application claim 18. The method of any of claims 11-16 further comprising adding interferon alpha to the lymphocytes.

Newly added claim 11 recites:

> 11. A method of inhibiting a virus by growing HCV in an environment having lymphocytes which produce Type 1 and Type 2 cytokine responses, and adding ribavirin and an alpha interferon to the environment in a concentration with the expectation of increasing the Type 1 response and suppressing the Type 2 response.

Newly added claims 12 and 13 add dosage limitations taken from Table 1 in the specification, again with the correction of the typographical error in the units from μg/ml to μM, as corrected in the parent application that issued as US 6150337.

Newly added claims 14 – 16 address the fact that the data presented in the specification is merely *in vitro* data rather than clinical data, and that it is contemplated that physicians would prescribe ribavirin, by itself or in combination with interferon, to treat viral infections merely on the *in vitro* data suggesting that these compounds "may" be beneficial in treating the infection, i.e., without clinical proof.

REQUEST FOR ALLOWANCE

Claims 1-16 are pending in this application. The applicant requests allowance of all pending claims.

Respectfully submitted,
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